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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
| 10/787,393  | 02/27/2004  | Tony Mikael Wahlroos | 108306-00024                    | 5309                        |
| 4372 7590 11/20/2007<br>ARENT FOX LLP<br>1050 CONNECTICUT AVENUE, N.W.<br>SUITE 400<br>WASHINGTON, DC 20036 |             |                      | EXAMINER<br>PAGE, BRENT T       |                             |
|   |             |                      | ART UNIT<br>1638                | PAPER NUMBER                |
|   |             |                      | NOTIFICATION DATE<br>11/20/2007 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

**Office Action Summary**

Application No.

10/787,393

Applicant(s)

WAHLROOS ET AL.

Examiner

Brent Page

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-15 and 17-52 is/are pending in the application.
- 4a) Of the above claim(s) 11-12, 15, 17, 21-22, and 26-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The Reply by Applicants filed on 08/29/2007 is hereby acknowledged. Any rejection or objection from the previous office action mailed on 05/31/2007 not addressed in the office action set forth below is considered hereby withdrawn in response to Applicants arguments when taken together with the claim amendments. Portions of the text of statutes pertaining to the office action not contained below may be found in the office action mailed on 05/31/2007.

#### ***Claim Rejections - 35 USC § 103***

Claims 1, 3-10, 18-20, and 23-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (US Patent 5003045), in view of Patten et al (US Patent 6413745), further in view of Puthigae et al (US Patent 6291666), and further in view of Josefsson et al (1987 The Journal of Biological Chemistry 262: 12196-12201). The claims remain rejected under 35 USC 103(a) for obviousness for the reasons of record on pages 6-10 as well as the reasons set forth below.

#### ***Response to Arguments***

Applicant's arguments filed 08/29/2007 have been fully considered but they are not persuasive.

Applicants urge primarily that Hoffman discloses insertion of a duplication of a 15 kDa zein sequence into the XbaI site located within the 3<sup>rd</sup> exon of the phaseolin gene, and that therefore the construct differs from the presently claimed invention in which the amino acid extension replaces the termination codon of the carrier.

This is not persuasive for multiple reasons. Firstly, this is not persuasive in that without demonstration of a surprising result, it is not readily apparent why it would not be obvious to place the amino acid extension in any location that does not disrupt the activity of the carrier protein, which is taught and described by Hoffman et al. Indeed, the feature of not disrupting the carrier protein is important enough to the invention to be a limitation in the instant claims, a limitation that is indeed met by Hoffman et al. In contrast, a feature being argued by Applicant to differ between the instant invention and that of Hoffman et al, namely the replacement of the termination codon, is not presently claimed. However, even if this particular limitation was claimed, it does not follow that such a modification would not be obvious. The presence or absence of the termination codon of the carrier protein within a construct would not be critical to the function of the invention as the full length of the carrier protein would be translated either way. The use of either the native termination codon or one provided in the construct would merely be a design choice and does not appear to be critical to the invention. Without clear evidence that this feature is critical to the claimed invention, and without clear evidence that this differs materially from the prior art, it is obvious to make such a design choice.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., replacement of termination codon) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants also urge that "Hoffman does not disclose the construct of Hoffman is not 'obtainable' by the method of present claims 6-8 and 23-25 which disclose a stable amino acid extension in the C-terminal end of the carrier protein."

This is not persuasive because even assuming Applicants intended to say that Hoffman doesn't disclose that the construct of Hoffman IS "obtainable" by the method of present claims 6-8 and 23-25, the claims in question do NOT recite that the stable amino acid extension is in the "C-terminal end of the carrier protein". As mentioned above, even if the claims did disclose this limitation, it is not readily apparent why this would not merely be a design choice, and thus obvious to one of ordinary skill in the art. Regardless, the method claims as they read now would still apply to the construct of Hoffman et al as originally interpreted in the previous office action on pages 4-5 of the now withdrawn 102 rejection as it applies to the current 35 USC 103(a) rejection. Namely, the sequence being fused "in frame" with the stable poly amino acid Extension (the zein sequence), is the phaseolin gene up to the third exon, which, falling short of the termination codon, meets the requirement of claim 1 that the nucleotide sequence lacks a termination codon. The remainder of the gene is fused to the stable amino acid extension and therefore the resultant expressed protein retains carrier function as required by the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the location of the amino acid extension in the C-terminal end of the carrier protein)

are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants further urge that Patten et al, Puthigae et al, and Josefsson et al alone or in combination do not teach or suggest an amino acid extension replacing the termination codon.

This is not persuasive because the claims, as discussed above, do not recite this feature.

Applicant also urges a surprising observation of unstable deletion variants necessitate the analyzing of constructs with the IVT system before transforming the constructs into plant hosts.

This is not persuasive because one of ordinary skill in the art would understand and appreciate the need to screen any insertion construct to determine whether or not the carrier protein retains its normal function. IVT systems, such as the one taught by Patten et al are commonly used in the art for such analyses and as demonstrated by Patten et al, used for a variety of analyses of transgenic constructs. It is not required that the motivation of one of ordinary skill in the art be the same as the motivation of the inventor for using a particular limitation of the invention, only that one of ordinary skill in the art would have been motivated to incorporate this limitation.

Applicants also urge that the references in the 103 rejection do not meet the limitation of a napin promoter from *Arabidopsis thaliana*.

This is not persuasive because the specification specifically indicates prior art of the napin promoter from *Arabidopsis thaliana*, and the office action asserted that the promoter used was merely a design choice. Applicants have not provided any evidence that it would not be obvious to use any promoter that directs expression in the seed of the plant. Furthermore the instant application lists several possible promoters, all of which are taught by the prior art that only share the characteristic of seed-specific expression, further supporting the Examiner's assessment that selection of promoter, is, in fact, a design choice that would have been obvious to one of ordinary skill in the art.

Claims 1, 3-10, 13-14, 18-20 and 23-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney (US Patent 5650554) in view of Patten et al (US Patent 6413745), further, in view of Puthigae et al (US patnet 6291666), and further in view of Josefsson et al (1987 The Journal of Biological Chemistry 262: 12196-12201). The claims remain rejected under 35 USC 103(a) for obviousness for the reasons of record on pages 6-10 as well as the reasons set forth below.

### ***Response to Arguments***

Applicant's arguments filed 08/29/2007 have been fully considered but they are not persuasive.

Applicants allege that the constructs taught by Moloney may not result in the oleosin carrier protein having a stable polyamino acid extension.

Absent evidence to the contrary, Moloney's disclosure is presumed valid. Mere allegations without evidence to support them, are not persuasive in coming to a conclusion that would dispute the teachings of Moloney. Absent evidence to the

Art Unit: 1638

contrary, the teaching of Moloney combined with the other references render the instant claims obvious to one of ordinary skill in the art.

Applicants further urge it would not have been obvious to those of skill in the art that "some of the constructs, which encode a fusion product having a C-terminal amino acid extension, may produce unstable deletion variants and be inefficiently translated, or may even result in a translation product that contains a shorter amino acid extension than the product obtained with a similar construct having less codons."

This is not persuasive because the limitations that Applicants cite as not being obvious are not contained in the claims. The claims do not recite a "C-terminal amino acid extension", nor do the claims recite specific lengths of amino acid extensions beyond the claimed range of 4 to 80 that is met by the cited art. Furthermore, it is not required that one of skill in the art appreciate that not all embodiments result in unstable deletion variants, but rather that one of ordinary skill in the art finds it obvious to perform the claimed steps of the method, which has been asserted in the previous office action.

Applicants also urge that Moloney teaches away from the use of promoters other than oleosin promoters.

This is not persuasive because Moloney merely teaches that in addition to other seed storage gene promoters, "Use of oleosin regulatory sequences provides an additional means by which to accomplish such modifications". This does not teach away from the use of other promoters, it merely suggests oleosin as an alternative. Moloney does not associate inoperability with any other seed-specific promoter sequence.



Applicants further urge that the other references do not teach the deficiencies of Moloney.

This is not persuasive for the reasons listed above. Applicants have failed to point out anything additional that they consider to be a “deficiency” and the other references teach the limitations as documented in the office action mailed on 05/31/2007. The Arabidopsis napin promoter is discussed above, but to reiterate, in response to the argument that this rejection does not render the use of the napin promoter from Arabidopsis thaliana obvious, this is not persuasive because the specification specifically indicates prior art of the napin promoter from Arabidopsis thaliana, and the office action asserted that the promoter used was merely a design choice. Applicants have not provided any evidence that it would not be obvious to use any promoter that directs expression in the seed of the plant. Furthermore the instant application lists several possible promoters, all of which are taught by the prior art that only share the characteristic of seed-specific expression, further supporting the Examiner’s assessment that selection of promoter, is, in fact, a design choice that would have been obvious to one of ordinary skill in the art.

No claims are free of the art.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (571)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/787,393  
Art Unit: 1638

Page 10

Brent T Page

RUSSELL P. KALLIS, PH.D.  
PRIMARY EXAMINER

*Russell Kallis*